

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claim 36 is amended and claim 40 is newly added by way of the instant communication. The amendments are fully supported by the application as filed and thus raises no issue of new matter.

After amending the claims as set forth above, claims 10 and 33-40 are currently pending in this application.

**Rejection under 35 U.S.C. § 112, First Paragraph**

The rejection of Claims 36-39 under 35 U.S.C. § 112, First Paragraph, for alleged lack of enablement is respectfully traversed.

In this rejection, the Examiner acknowledges that the specification is enabling for isolated bacterium, however, alleges that “[t]he specification does not reasonably provide enablement for the breadth of the claims, which encompass non-isolated bacteria comprising the previously described vector.” Applicant respectfully submits that, contrary to the Examiner’s assertion, one of ordinary skill could make and use bacterium as previously claimed without undue experimentation. In this regard, Applicant respectfully submits that a system for thiamin-deficiency therapy is but one of many uses for a bacterium as previously claimed and that one of ordinary skill would appreciate that there are uses for such bacteria that would not require the bacterium to be isolated. However, in order to reduce the issues and advance prosecution, claim 36 has been amended to recite that the bacterium are isolated. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 112, First Paragraph**

The rejection of claims 34-35 under 35 U.S.C. § 112, First Paragraph as allegedly failing to comply with the written description requirement is respectfully traversed.

The Examiner acknowledges that the nucleic acids of claims 34-35 have “a particular nucleic acid structure” yet rejects the claims on the basis that the claimed nucleic acids allegedly “fail to be described with a particular function.” See Office Action at page 5, lines 8-11.

The proper standard for determining compliance with the written description requirement of 35 U.S.C. § 112, first paragraph, is whether the specification reasonably conveys to the skilled artisan that the inventor was in possession of the claimed invention as of the filing date. See MPEP § 2163.02 (citing *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 USPQ 177, 179 (Fed. Cir. 1985)). The subject matter of the claimed invention need not be described literally in the specification in order to satisfy the requirements of 35 U.S.C. § 112, first paragraph. *Id.* In a careful analysis of the written description requirement provided by the Patent and Trademark Office in its *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶1*, “Written Description” Requirement, it is stated that an adequate written description “may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.” 66 Fed. Reg. 1099, 1105 (2001) (emphasis added).

Instant claim 34 is directed to a purified, enriched, or isolated nucleic acid sequence, wherein the nucleic acid sequence is at least 90% identical to a portion at least 200 nucleotides in length of the *N. gruberi* thiaminase sequence as set forth in SEQ ID NO:3. Each and every nucleotide of SEQ ID NO:3 is unambiguously described in the application. Selecting a portion of SEQ ID NO:3 that is 200 nucleotides in length is a trivial task to one of ordinary skill in the art as is determining the number of nucleotide bases that would constitute 90% of the selected

portion of SEQ ID NO:3. Accordingly, Applicant respectfully submits that the specification provides ample written description to demonstrate that the inventor was in possession of the entire genus of nucleotide sequences encompassed by the instant claims.

Applicant respectfully submits that the Examiner's assertion at pages 4-5 of the office action suggesting that the fact that a 200 nucleotide segment is 18.7% percent of the total length of SEQ ID NO:3 is irrelevant to a determination as to whether there is adequate written description for the instant claims. In this regard, each and every nucleotide of SEQ ID NO:3 is provided in the application, therefore each nucleotide of every possible 200 nucleotide segment of SEQ ID NO:3 is also inherently described in the application. As described above the determination of sequences that are 90% identical to such segments is trivial to one of ordinary skill. Thus, because each amino acid of SEQ ID NO:3 is explicitly described in the application, the fact that the instant claims need only encompass a portion (e.g., 18.7%) of the fully described sequence bears no relevance as to whether the sequence, or segments thereof, are described.

Applicant respectfully submits that the Examiner's reliance on *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed Cir. 1997) is misplaced. In *Lilly*, the specification provided a description of the nucleotide sequence of only rat insulin cDNA. The relevant claims of the *Lilly* '525 patent at issue were directed to human insulin cDNA. The specification provided guidance as to how one could determine the sequence of human insulin cDNA, however, it did not disclose any actual sequence of human insulin cDNA. The court held that because the application provided no sequence of the human insulin cDNA, the claims to human cDNA were not adequately described under §112, first paragraph. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, ("[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties' not a mere wish to plan for obtaining the claimed chemical invention"). Applicant respectfully submits that the instant case is clearly distinguishable from *Lilly*. In particular, unlike *Lilly* which provided no description of any sequence to the claimed human insulin cDNA,

the instant application explicitly discloses each and every nucleotide of the claimed sequence, SEQ ID NO:3. Accordingly, because the precise structure of SEQ ID NO:3 is explicitly described, Applicant respectfully submits that under *Lilly*, requiring a function of the sequence in the claim is not necessary for the claims to meet the written description requirement.

Newly added dependent claim 40 further obviates the above rejection by requiring that the nucleic acid sequence encodes a protein having thiaminase activity.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the written description rejection.

### **Conclusion**

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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